UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

WALGREEN CO., THE KROGER CO., ALBERTSONS COMPANIES, INC, and H-E-B, L.P., Plaintiffs, v. TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC., Defendants.	Civil Action No. 2:25-cv-372 JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Albertsons Companies, Inc. and H-E-B, L.P. sue Defendants Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Defendants" or "Teva") for violations of the federal antitrust laws relating to the market for Copaxone and its generic equivalents. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. Copaxone® ("Copaxone") is Teva's injectable drug product indicated to reduce relapses in patients with relapsing-remitting multiple sclerosis, a condition characterized by inflammation of the insulating membranes surrounding nerve fibers in the central nervous system. Glatiramer acetate is the active ingredient in Copaxone. Teva received FDA approval for Copaxone in 1996 and launched shortly thereafter. From 2015 through 2017, Teva's Copaxone U.S. revenues exceeded $3 billion annually.

2. Generic Copaxone first entered the market in June 2015 and additional competitors entered thereafter:

Date	Manufacturer	Product
June 18, 2015	Sandoz	generic Copaxone 20mg
October 4, 2017	Mylan	generic Copaxone 20mg
October 4, 2017	Mylan	generic Copaxone 40mg
February 13, 2018	Sandoz	generic Copaxone 40mg

3. Despite the availability of these more affordable generic Copaxone products, Teva continued to dominate the market by unlawfully suppressing generic competition to branded Copaxone. It was not until the Department of Justice ("DOJ") filed its lawsuit against Teva for violations of the federal Anti- Kickback Statute on August 18, 2020, and the Committee on Oversight and Reform of the U.S. House of Representatives ("House Committee") issued its report on September 30, 2020 (the "Staff Report"), that Teva's multifaceted monopolization scheme came to light.

4. As revealed by the Staff Report, Teva unlawfully suppressed generic competition for Copaxone by, among other things: (i) entering into exclusionary contracts with pharmacy benefits managers ("PBMs") and certain of their associated specialty pharmacies that effectively barred the dispensing of generic Copaxone; (ii) engaging in a coercive product switch to thwart generic competition; (iii) pursuing an aggressive "Dispense as Written" campaign fueled by misinformation about generic Copaxone; and (iv) paying illegal kickbacks and otherwise manipulating patient copays to boost sales of brand Copaxone. By suppressing generic competition to Copaxone, Teva caused Plaintiffs to purchase more units of expensive brand Copaxone and fewer units of less expensive generics, causing Plaintiffs to suffer overcharges on their Copaxone purchases which continue to the present day.

5. Teva's scheme to monopolize had at least five components.

6. First, Teva engaged in serial sham petitioning that included (a) eight unsuccessful citizen petitions to the FDA, (b) numerous, mostly unsuccessful patent infringement actions against generic manufacturers seeking approval to market generic versions of Copaxone, and (c) two unsuccessful actions against the FDA. These proceedings were filed without regard to their merit, solely to trigger automatic 30-month stays or otherwise delay FDA approval of applications to market generic versions of Copaxone.

7. Second, Teva suppressed generic competition by entering into exclusionary contracts, pursuant to which PBMs agreed to exclude generic Copaxone from their formularies and certain of their associated specialty pharmacies agreed to dispense only the brand product, even when the generic was prescribed.

8. Third, Teva engaged in a coercive product switch to prevent the automatic generic substitution that otherwise would have occurred, commenting internally that the new product was an "Opportunit[y]" to create a "Barrier to Generic entrance." Specifically, as generic Copaxone 20mg neared market entry, Teva launched a new 40mg dosage, a pursuit senior Teva scientists were "strongly against" because it had "no scientific rationale/value." Teva then switched the market to the new dosage by, *inter alia,* enlisting PBMs to lobby doctors to convert all patients to the 40mg and by tying rebates on Copaxone 20mg to the PBM's inclusion of Copaxone 40mg on the formulary. Within six months of generic entry, nearly 80% of Copaxone patients had been converted to the 40mg dosage, allowing Teva to avoid the generic substitution that otherwise would have occurred.

9. Fourth, when Mylan launched the first generic Copaxone 40mg (and the second Copaxone 20mg), Teva responded by implementing an aggressive "Dispense as Written" campaign based in part on representing to doctors, without any scientific basis, that generic

Copaxone was less effective than the brand product. Within four months of the launch of generic Copaxone 40mg, more than 77% of Copaxone 40mg prescriptions bore the notation "Dispense as Written," preventing generic substitution and foreclosing competition to a significant portion of the market.

10. Fifth, Teva paid millions of dollars in illegal kickbacks to charitable foundations with the purpose and understanding that the "donations" would be used to subsidize patients' out-of-pocket costs for brand Copaxone only, thereby driving up sales of the brand product. This price distortion was intended to, and succeeded in, suppressing competition. In a lawsuit filed against Teva, the DOJ alleges that this conduct violates the federal anti-kickback statute, 42 U.S.C. § 13320a-7b(b) (the "Anti-Kickback Statute") and resulted in Medicare paying out hundreds of millions of dollars in false claims.

11. Teva's anticompetitive scheme to suppress generic competition was successful, causing Plaintiffs (and their assignors) to purchase more units of expensive branded Copaxone and fewer units of less expensive generic Copaxone, resulting in overcharges.

12. Plaintiffs and their assignors have suffered overcharges on Copaxone 20mg purchases, which began in June 2015, when the first generic Copaxone 20mg product became available, and continue through the present. Plaintiffs and their assignors have suffered overcharges on Copaxone 40mg purchases, which began in October 2017, when the first generic Copaxone 40mg became available, and continue through the present.

13. Plaintiffs seek damages, permanent injunctive relief and all other appropriate relief for Teva's wrongdoing.

II. PARTIES

14. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates

retail stores in several states at which it dispenses prescription drugs, including Copaxone, to the public. Walgreen brings this action in its own behalf and as the assignee of AmerisourceBergen Drug Corporation, a pharmaceutical wholesaler, which during the relevant period purchased Copaxone directly from Teva and generic Copaxone directly from other manufacturers for resale to Walgreen and which has expressly assigned its claims arising out of those purchases to Walgreen.

15. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Copaxone, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal Health, Inc., a pharmaceutical wholesaler, which during the relevant period purchased Copaxone directly from Teva and generic Copaxone directly from other manufacturers for resale to Kroger and which has expressly assigned its claims arising out of those purchases to Kroger.

16. Plaintiff Albertsons Companies, Inc. ("Albertsons") is a Delaware corporation having its principal place of business at 250 Parkcenter Boulevard, Boise, Idaho 83706. Albertsons' affiliates own and operate retail stores in several states at which they dispense prescription drugs, including Copaxone, to the public. Albertsons brings this action in its own behalf and as the assignee of McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which during the relevant period purchased Copaxone directly from Teva and generic Copaxone directly from other manufacturers for resale to Albertsons' affiliates and which has expressly assigned its claim arising out of those purchases to Albertsons.

17. Plaintiff H-E-B, L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores at which it dispenses prescription drugs, including Copaxone, to the public.

HEB brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Copaxone directly from Teva and generic Copaxone directly from other manufacturers for resale to HEB and which has expressly assigned its claim arising out of those purchases to HEB.

18. Defendant Teva Pharmaceuticals Industries, Ltd. ("Teva Ltd.") is a worldwide pharmaceutical company engaged in the development, manufacturing, marketing, and sale of pharmaceutical products. Teva Ltd. is an Israeli company, having its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel.

19. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, having its principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054. Teva USA does business throughout the United States, including in this district.

20. Defendant Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation, having its principal place of business at 11100 Nall Ave, Overland Park, Kansas, 66211. Teva Neuroscience does business throughout the United States, including in this district.

21. Defendant Teva Sales & Marketing, Inc. ("Teva Sales") is a Delaware corporation, having its principal place of business at 11100 Nall Avenue, Overland Park, Kansas 66211. Teva Sales does business throughout the United States, including in this district.

22. Teva USA controls, directs, and supervises the sales and marketing activities of Teva Neuroscience and Teva Sales, as well as their employees.

23. Teva Ltd. controls, directs, and supervises the sales and marketing activities of Teva USA, Teva Neuroscience, and Teva Sales, as well as their employees.

24. Teva USA, Teva Neuroscience, and Teva Sales are subsidiaries of Teva Ltd.

III. JURISDICTION AND VENUE

25. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, and seeks damages and injunctive relief pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26.

26. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

27. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b)-(d) because, during the relevant time period, Defendants resided, transacted business, were found, or had agents in this district and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

28. This Court has personal jurisdiction over Defendants because they, either directly or through the ownership and/or control of their subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this district; (b) had and maintained substantial aggregate contacts with the United States as a whole, including in this district; and (c) were engaged in an illegal scheme that was directed at, and had a direct, substantial, reasonably foreseeable, and intended effect of, causing injury to the business or property of persons and entities residing, located, or doing business in the United States, including in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

29. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's

choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

30. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Copaxone, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) is obligated to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

31. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

32. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power or monopoly power. The result of the market imperfections and marketing practices described above is to allow brand

manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

33. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

34. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

35. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

36. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). *See* Drug Price

Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. It must only show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug. In other words, the ANDA must demonstrate that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating. For injectable drugs, the equivalent rating is "AP."

37. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

38. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) Generic Defendants, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

39. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had increased many-fold to $300 billion.

D. Paragraph IV Certifications

40. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

41. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement Action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

42. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV

certification typically gets a period of protection from competition from generic versions of the drug marketed by other ANDA filers. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This 180-day exclusivity period is extremely valuable to generic companies. When only one generic is on the market, the generic price, while lower than the branded price, is much higher than it is after multiple generic sellers enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generics on the market. Being able to sell at the higher price for six months may be worth hundreds of millions of dollars.

E. Benefits of Generic Drugs

43. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as those operated by Plaintiffs, a generic drug typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies view competition from generic drugs as a grave threat to their bottom lines.

44. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists dispense the generic version whenever possible when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state

has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for brand prescriptions unless the prescribing physician has specifically countermanded that substitution by writing "dispense as written" or equivalent language on the prescription.

45. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

46. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market.

47. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an "authorized generic" is literally identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both the ANDA filer's generic drug and the authorized generic and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

48. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA. Valid and infringed patents may lawfully prevent generic competition, at least for a period, but manufacturers can abuse the system to use invalid or non-infringed patents to unlawfully delay generic competition.

49. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

50. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. A patent holder always bears the burden of proving infringement.

51. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

52. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art; (ii) its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention; (iii) an inventor,

an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (iv) when the invention claimed in a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

53. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

54. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

55. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

F. The Biologics Price Competition and Innovation Act likewise allows for approval of biosimilar drugs and enables competition with their biologic counterparts.

56. Biologics are not new. They include vaccines, first developed in the late eighteenth century. But technological advances in the past few decades have resulted in more biologics coming to market than ever before.

57. The approval process for a new biologic drug is also regulated by the FDCA and is similar to that for the brand name version of a small molecule drug. A manufacturer of a biologic may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in 42 U.S.C. § 262. The pathway for approval for new biologics is set forth in 42 U.S.C. § 262(a). Under that subsection, the drug manufacturer submits a Biologic License Application ("BLA"), which must include data similar to that included in an NDA; the FDAmay license a new biologic if, among other things, the manufacturer demonstrates that it is "safe, pure, and potent."

58. The statute also prescribes an alternative, abbreviated route for FDA approval of biosimilars, set forth in 42 U.S.C. § 262(k), which was enacted as part of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). While the first approved version of a small molecule drug is commonly known as the "brand name" drug, the BPCIA refers to the first approved version of a biologic as the "reference" biologic. Biosimilar versions of biologic products are in some sense analogous to generic versions of brand name small molecule drugs.

59. However, the biologics/biosimilars regulatory system differs from that governing small molecule drugs in certain key respects. Because biologics "are derived from living cells, biologics can never be exactly reproduced or copied like [traditional] generics," biosimilars must undergo a more rigorous and expensive process than generic drugs to receive FDA approval. A biosimilar manufacturer must show that its product is "highly similar" to the

reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."

60. Even once a biosimilar receives FDA-approval, it will not be automatically substitutable for the reference biologic product. Unlike generic drugs, the biosimilar must undergo a separate interchangeability determination before it will be considered substitutable. The FDA has made only two such "interchangeability" determinations to date, both of which occurred in 2021.

61. In sum, while biosimilars are in some ways analogous to generic drugs, there are additional hurdles a biosimilar must overcome before it will be deemed automatically substitutable for the reference biologic product.

G. Misuse of citizen petitions delays FDA approval of generic drugs.

62. Section 505(j) of the Food, Drug and Cosmetic Act creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

63. Citizen petitions provide a forum for individuals to express and support their genuine concerns about safety, scientific, or legal issues regarding a product any time before, or after, its market entry. Other than the form it should take, the regulations place no restrictions on the subject matter of a citizen petition.

64. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

65. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay the FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

66. A citizen petition may be filed to request that the FDA take action regarding drug approval requirements, including those involving generic drugs. To successfully move the FDA to grant this type of request, the petition must include supportive, clinically meaningful data and the requested relief must be consistent with the Hatch-Waxman statutory and regulatory framework and within the power of the FDA to grant.

67. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies have sought to compensate for dwindling new product pipelines. In such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing, delaying the approval of the generic product while the FDA evaluates the citizen petition.

68. Delaying generic competition is a lucrative strategy for an incumbent manufacturer. Given the marketplace's preference for generic products over brand products, the cost of filing an improper citizen petition may be trivial compared to the value of securing even a few months delay in a generic rival's entry into the market.

69. Even the FDA, which is often hesitant to comment on existing law, has at times spoken out against the current citizen petition process. Former FDA Chief Counsel Sheldon

Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

70. The FDA continues to have serious concerns about the abuse of the citizen petition process for anticompetitive purposes and noted in a 2020 report to Congress that "the Agency continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."

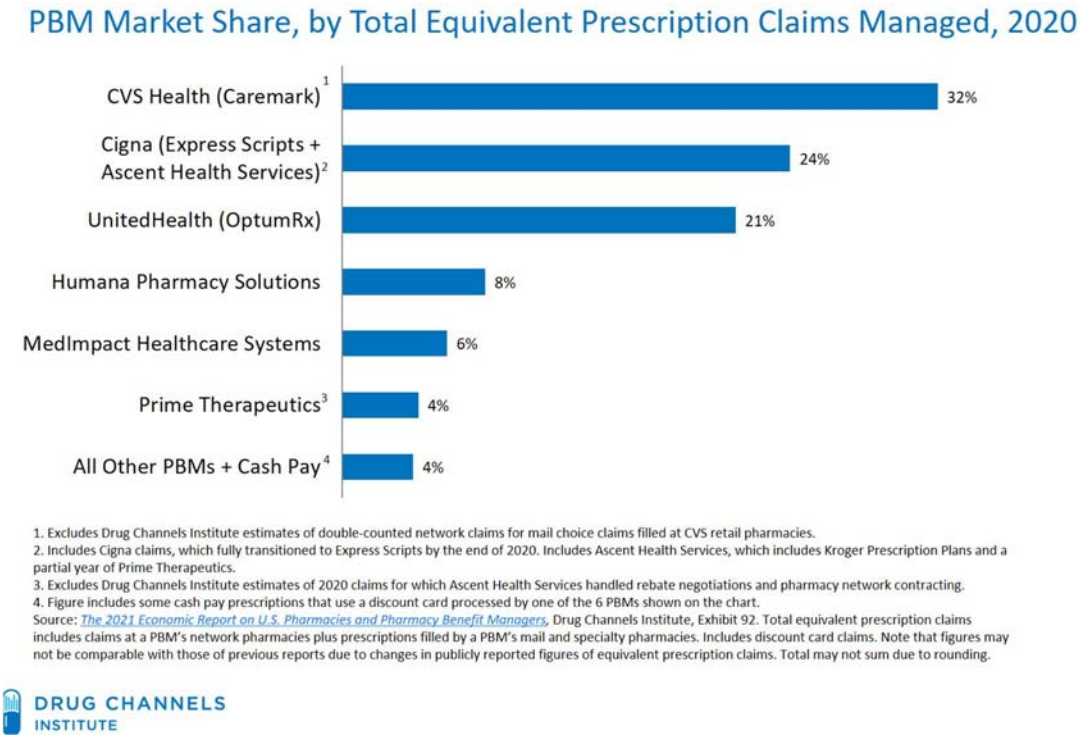
71. It is the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval until after its consideration of and response to a citizen petition was complete. On this subject, Gary Buehler, a former Director of the Office of Generic Drugs, acknowledged that "[i]t is very rare that petitions present new issues that CDER [Center for Drug Evaluation and Research] has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

H. Role of PBMs and Specialty Pharmacies

72. PBMs are third-party entities that manage prescription drug benefits on behalf of their clients, which include health insurance companies, self-funded health plans, large employers, and governmental entities. PBMs create pharmacy networks. This includes mail order and specialty pharmacies in addition to the more familiar chain and independent pharmacies. Many mail-order pharmacies and some specialty pharmacies are either owned by a PBM or share common ownership with a PBM.

73. Another major role of the PBM is to create and maintain a drug formulary for the PBM's clients. A formulary is a list of prescription drugs for which the health plan will reimburse pharmacies on behalf of the plan's members. The purpose behind the drug formulary is to provide quality care using the most cost-effective options. If a drug is not included on a formulary, the health plan generally will not cover the cost of the drug. Thus, if a doctor prescribes a drug that is not on the formulary, the patient will be required to pay the entire cost of the drug out-of-pocket.

74. The PBM market is highly concentrated. Indeed, just three PBMs comprise more than 75% of the market:



75. In sum, through their control of formularies and pharmacy networks, PBMs have a prominent role in determining what drugs will be accessible to patients and at what cost. The PBMs' decisions may be influenced by drug manufacturers' rebating strategies, which raises special concerns where rebates are used by a monopolist to foreclose (rather than promote) competition.

V. OPERATIVE FACTS

A. Since launching the product in 1997, Teva has made billions of dollars on Copaxone.

76. Approximately one million Americans suffer from multiple sclerosis, an incurable, often progressive, life-altering disease that afflicts the central nervous system. Those with multiple sclerosis may experience a wide range of symptoms, including weakness, numbness, tremors, loss of vision, blurry vision, slurred speech, fatigue, and dizziness.

77. The vast majority (approximately 85%) of those diagnosed with MS are diagnosed with relapse-remitting MS ("RRMS"), a condition characterized by inflammatory attacks on the layers of insulating membranes surrounding nerve fibers in the central nervous system. Copaxone is Teva's injectable drug product with the active ingredient glatiramer acetate indicated for reduction of the frequency of relapses in patients with RRMS.

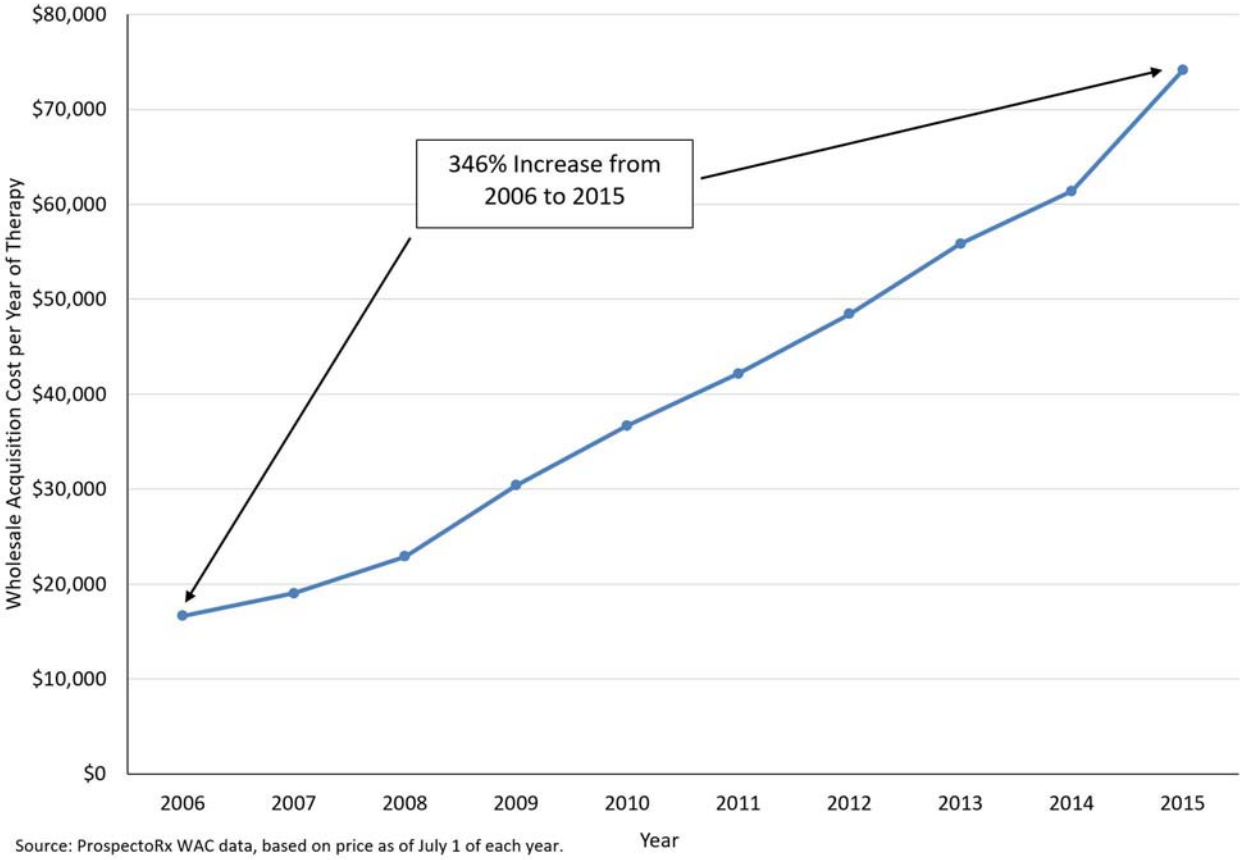
78. Copaxone received FDA approval in December 1996 in a 20mg vial formulation. In February 2002, the FDA approved Copaxone 20mg for daily injection. Teva ultimately obtained nine patents claiming the Copaxone 20mg product, including the drug substance itself, pharmaceutical compositions comprising Copaxone, methods of treating multiple sclerosis using Copaxone, and methods of making Copaxone. Seven of these patents were listed in the Orange Book with an expiration date of May 24, 2014. The other two patents were not listed in the Orange Book because they only claimed processes for manufacturing Copaxone.

79. In 2013, Teva submitted a supplemental New Drug Application for a 40mg dosing strength of Copaxone to be administered three times per week. The FDA approved Copaxone 40mg on January 28, 2014. Teva eventually obtained five patents that were listed in the Orange Book for Copaxone 40mg with an expiration date of August 19, 2030.

80. Teva has collected more than $34 billion in Copaxone net U.S. revenue since launching the drug. In 2016 alone (the first full year following generic entry), Teva's net U.S. revenue for Copaxone was $3.3 billion. In recent years, Copaxone accounted for approximately one fifth of Teva's North American net revenues.

81. On December 10, 2021, the U.S. House of Representatives Committee on Oversight and Reform issued a report entitled "Drug Pricing Investigation – Majority Staff Report" that analyzed drug manufacturers' price increases, including Teva's price increases on Copaxone. According to the report, Teva has imposed more than twenty-five price hikes on Copaxone, increasing the price to $85,400/year, representing an 825% price increase since the product first launched. Over the period 2006-2015 alone, Teva increased the price of Copaxone 20mg by more than three-fold:

Figure 1: Wholesale Acquisition Cost per Year of Therapy, Copaxone 20 mg, 2006-2015



Source: ProspectoRx WAC data, based on price as of July 1 of each year.

B. Multiple generic manufacturers have sought to bring generic Copaxone to market.

1. Sandoz brought generic versions of the 20mg and 40mg to market in 2015 and 2018, respectively.

82. On or about December 27, 2007, Sandoz submitted ANDA No. 090218 for generic Copaxone 20mg to the FDA. On or about July 10, 2008, Sandoz sent a Paragraph IV notice letter to Teva asserting that the patents listed in the Orange Book for Copaxone 20mg were invalid or not infringed by Sandoz's ANDA product.

83. On or about February 14, 2014, Sandoz submitted ANDA No. 206921 for generic Copaxone 40mg to the FDA. On or about August 27, 2014, Sandoz sent a Paragraph IV notice letter to Teva asserting that the '250 and '413 patents were invalid or not infringed by Sandoz's

ANDA product. Sandoz subsequently sent similar Paragraph IV notice letters to Teva with respect to the ’302 and ’776 patents.

84. On April 16, 2015, the FDA approved Sandoz’s ANDA for its generic Copaxone 20mg product.

85. On June 18, 2015, Sandoz launched its generic Copaxone 20mg product, marketed as Glatopa® (“Glatopa”). At the time of launch, Glatopa was the first generic Copaxone product available at 20mg strength.

86. On February 12, 2018, the FDA approved Sandoz’s generic Copaxone 40mg product. On February 13, 2018, Sandoz launched generic Copaxone 40mg product. At launch, Sandoz’s was the second generic Copaxone 40mg product to enter the market.

2. Mylan brought generic versions of both dosages to market in 2017.

87. On June 26, 2009, Mylan submitted ANDA No. 091646 for generic Copaxone 20mg to the FDA. On or about September 16, 2009, Mylan sent a Paragraph IV notice letter to Teva asserting that the patents listed in the Orange Book for Copaxone 20mg were invalid or not infringed by Mylan’s ANDA product.

88. On or about February 12, 2014, Mylan submitted ANDA No. 206936 for generic Copaxone 40mg to the FDA. On or about August 28, 2014, Mylan sent a Paragraph IV notice letter to Teva asserting that the ’250 and ’413 patents were invalid or not infringed by Mylan’s ANDA product. Sandoz subsequently sent similar Paragraph IV notice letters to Teva with respect to the ’302 and ’776 patents.

89. On October 3, 2017, the FDA approved Mylan’s ANDAs for the 20mg and 40mg generic Copaxone products.

90. On October 4, 2017, Mylan launched its generic Copaxone 20mg and 40mg products. Mylan’s generic Copaxone 40mg product was the first generic Copaxone product

available in the United States for 3-times-a-week injection that was an AB-rated substitute for Teva's 40mg Copaxone product. At launch, Mylan's generic Copaxone 20mg product was the second AP-rated substitute for Teva's 20mg Copaxone product in the United States market.

3. Additional generic manufacturers filed ANDAs but have not received FDA approval.

91. Other generic manufacturers, including Dr. Reddy's Laboratories Inc. ("Dr. Reddy's"), Synthon Pharmaceuticals, Inc. ("Synthon"), and Amneal GmbH ("Amneal"), have filed ANDAs for generic Copaxone 40mg, but these ANDAs have not yet received final approval from the FDA.

C. Teva engaged in extensive anticompetitive conduct to prevent generic competition.

92. Although generic manufacturers did eventually succeed in bringing generic Copaxone to market, Teva engaged in extensive efforts to block and otherwise delay generic entry. In describing this conduct, a federal court pointedly stated: "In 1995, Teva submitted an NDA for Copaxone, which FDA approved on December 20, 1996. . . . **Since that time, Teva has pursued every available avenue to prevent other glatiramer acetate products from coming to market**." *Teva Pharmaceuticals USA, Inc. v. United States Food and Drug Administration,* 514 F. Supp. 3d 66, 81 (D.D.C. 2020) (emphasis added). Teva's efforts to prevent generic entry have included engaging in sham patent litigation, filing numerous citizen petitions, and pursuing baseless lawsuits against the FDA to have Copaxone regulated as a biologic.

1. Teva attempted to delay entry of generic Copaxone 40mg by engaging in sham patent litigation.

93. Following the launch of Copaxone 20mg in 1997, Teva enjoyed a period of market exclusivity afforded by its patents, which ended in May 2014.

94. Following the end of Teva's period of exclusivity in 2014, Mylan, Sandoz and other generics entering the market should have quickly gained market share, driving prices down by 85% or more within the first year. To prevent this, in 2014, Teva began switching patients to Teva's new, three-times-weekly 40mg Copaxone product, which it sought to protect from generic competition by obtaining patents on the three-times-weekly dosing frequency.

95. On their face, the patents claiming the 40mg formulation and dosing regimen protected Copaxone 40mg from generic competition until August 2030. However, Teva knew that it would not win patent litigation over those patents, because the patents were invalid as obvious. Indeed, Teva's own submissions to the FDA reveal that Teva believed that the three-times-weekly dosing regimen was obvious. For example, in December 2009, Teva submitted a clinical protocol to the FDA, in which Teva stated that, after finding the 40mg and 20mg dosage to be equally effective: "the natural next step [was] to reduce the dosing regimen of [Copaxone] and find the optimal regimen that [would] improve the convenience of treatment and reduce the burden and adverse events associated with daily subcutaneous injections." The Federal Circuit ultimately agreed with Teva, concluding unanimously in 2018 that Teva's patents directed to the 40mg formulation were "invalid as obvious under 35 U.S.C. § 103." *In re Copaxone Consol. Cases*, 906 F.3d 1013, 1016 (Fed. Cir. 2018).

96. Nevertheless, in an effort to block generic entry for Copaxone 40mg, Teva obtained the dosage frequency patents, which it listed in the Orange Book, and then filed baseless patent litigation against ANDA filers asserting that those patents were infringed. Specifically, between 2014 and 2017, Teva sued Mylan, Sandoz (and Sandoz's commercialization partner Momenta Pharmaceuticals, Inc.), Dr. Reddy's, Synthon (and Synthon's commercialization partner Pfizer Inc.), and Amneal for infringement of the '250, '413,

'302, and '776 dosage frequency patents in relation to the generic manufacturers' ANDA applications.

97. Every tribunal to review Teva's 40mg three-times-a-week patents, including the District Court, the Patent Trial and Appeal Board and the Federal Circuit, found the dosage regimen obvious over the prior art. The district court concluded that Teva's 40mg three-times-a-week patents were "**nothing more than 'life-cycle management'—an attempt to continue to monopolize a multi-billion-dollar market for a blockbuster drug.**"

98. Teva filed patent lawsuits against its putative generic competitors without regard to the validity of the patents or the merits of the infringement claims but rather solely for the purpose of delaying the entry of generic versions of Copaxone. Teva has used sham patent litigation against its generic competitors as an anticompetitive weapon to delay and suppress generic competition.

2. Teva filed a series of meritless citizen petitions over a seven-year period.

99. From 2008 to 2015, Teva filed eight citizen petitions with the FDA, seeking to block approval of ANDAs for generic Copaxone. Specifically, Teva's citizen petitions requested that the FDA deviate from the well-established ANDA approval process and refuse to approve any generic version of Copaxone unless it had undergone a full set of clinical trials.

100. If these requests had been granted, competitors would have been barred from using the normal routes for generic drug approval.

101. Each of Teva's eight citizen petitions was denied or withdrawn. In response to the denial of one of its citizen petitions, Teva sued the FDA and sought to "bar[] FDA from approving any application for a putative generic version of Copaxone® that does not comply with the conditions requested in Teva's citizen petition." That request was also denied, and the case dismissed.

102. Ironically, Teva has defended itself in the face of these serial filings and subsequent denials (in a separate suit alleging, *inter alia,* racketeering and consumer fraud) by arguing "citizen petitions are almost never granted."

103. It is widely known throughout the pharmaceutical industry that the FDA will postpone approval of an ANDA until any related citizen petitions are resolved. Indeed, it was not until April 16, 2015, the same day that the last of Teva's citizen petitions was denied, that the first generic Copaxone product was approved. Teva's flurry of citizen petitions caught the attention of antitrust scholar Michael Carrier, who described them as "a particularly glaring example of a company's aggressive use of the citizen petition process."

3. Teva filed sham lawsuits against the FDA.

104. Teva also filed two unsuccessful lawsuits against the FDA relating to Copaxone. The first case was filed in May 2014 challenging the denial of one of Teva's citizen petitions. That case was dismissed after the court found that the case was "not ripe and therefore the Court lacks jurisdiction." *Teva Pharm. Indus. Ltd. v. Sebellius*, No. 14-cv-786 (D.D.C. May 14, 2014), ECF No. 36. The second case against the FDA was filed in March 2020 and sought to force the FDA to treat Copaxone as a biologic.

105. As discussed above, the Biologics Price Competition and Innovation Act or BPCIA governs biologics and biosimilars. By March 23, 2020, the FDA was required to identify the pharmaceutical products that should be transitioned to biological product status. On March 24, 2020, the day following this deadline, Teva filed a lawsuit against the FDA alleging that the agency's denial of Teva's request to transition Copaxone to biologic product status was a violation of federal law.

106. Teva's motivation was clear. The automatic substitution laws that apply to generic drugs do not apply to biosimilars. Moreover, a biosimilar cannot be substituted for a biologic

unless and until the FDA has made a separate, additional determination regarding "interchangeability." At the time Teva filed its lawsuit against the FDA, the FDA had not made this interchangeability determination for any product. Thus, if Teva had prevailed in its lawsuit, a pharmacist would have been prevented from dispensing a generic Copaxone product unless it had been specifically prescribed.

107. On December 31, 2020, the district court denied Teva's motions for summary judgment and granted the motions for summary judgment filed by the FDA and by the intervenor- defendants, Mylan, and Sandoz. In its decision, the court made clear its view that Teva's lawsuit was nothing more than "**yet another effort [by Teva] to stifle Copaxone competitors**."

D. Teva's conduct was part of a global campaign to exclude generic competition and drive up brand Copaxone sales.

108. On March 4, 2021, the European Commission ("EC") announced that it "has opened a formal antitrust investigation to assess whether the pharmaceutical company Teva has illegally delayed the market entry and uptake of medicines that compete with its blockbuster multiple sclerosis drug Copaxone." The EC further explained that, "[i]f proven, Teva's behaviour may amount to an abuse of dominant position. . . ." According to the EC, this "is the Commission's first formal investigation into potential abuses relating to the misuse of patent procedures and exclusionary disparagement of competing products in the pharmaceutical industry."

109. Teva also pled guilty to violating the Foreign Corrupt Practices Act ("FCPA") and paid approximately $520 million in criminal and civil penalties to settle claims that Teva bribed medical professionals and government officials in Russia, Ukraine, and Mexico to drive up Copaxone sales. This is the largest criminal penalty ever imposed against a pharmaceutical company for FCPA violations.

110. Following generic entry, Teva has continued to dominate the market for Copaxone and its generic equivalents by illegally suppressing competition and frustrating generic substitution. Although a brand manufacturer's market share typically falls to 10% or less within one year of generic entry, Teva's exclusionary scheme enabled it to maintain a majority of the Copaxone market for years following generic entry.

E. Teva thwarted generic competition by switching the market from 20mg to 40mg Copaxone.

111. Drug manufacturers can and do bring new products to market without giving rise to liability under the antitrust laws. However, drug manufacturer conduct comes under scrutiny where, as here, the old product is facing loss of exclusivity; the new product represents an insignificant change; and the manufacturer uses coercive tactics and/or misinformation about the generic to pressure a switch to the new product.

112. The 40mg product "did not demonstrate an enhanced efficacy" and, internally, Teva executives acknowledged that "every other day over once daily does not represent a significant improvement in convenience." In fact, senior Teva scientists were "strongly against" development of the 40mg product because it had "no scientific rationale/value." Teva's true motivation for bringing Copaxone 40mg to market, and engaging in the coercive campaign to switch patients from the 20mg product to the 40mg product, was to foreclose generic competition in the face of Teva's impending loss of market exclusivity for the 20mg product. Teva's product switch succeeded in suppressing generic competition because a generic that differs from the brand product in terms of dosage cannot be automatically substituted for the brand product.

1. The 40mg product was launched to create a "barrier to generic entrance."

113. In late 2007, Sandoz filed its ANDA for generic Copaxone 20mg and in July 2008, Sandoz sent a Paragraph IV notice to Teva.

114. At that time, Teva had been conducting clinical trials comparing the efficacy of a new 40mg daily Copaxone to the existing 20mg Copaxone product. However, on July 7, 2008, Teva announced that its Phase III clinical trial had determined that there was no difference in efficacy between the 40mg product and the 20mg product. Almost immediately, Teva pivoted to examining whether it could stave off generic competition by instead changing the dosage regimen.

115. In internal emails with Teva's Senior Director of Innovative Projects regarding Copaxone Life Cycle Management, one executive asked, "Can we patent the frequency?" The author continued: "This is also a long-term plan, assuming Phase II and Phase III bringing us to 2016 – **still relevant?**" (emphasis added).

From: [redacted]
Sent: Tuesday, August 26, 2008 8:26 PM
To: [redacted]
Cc: [redacted]
Subject: Re: brief update from GIR meeting on GA LCM

Thanks for the update. A few points:
1. The limiting step with GA is the density of the solution. I assume that [redacted] has the information for the 60mg back from the days we have worked on the 80mg.
2. Please consider the ISR we saw in the rats with the 80mg (so we may not want to go to high).
3. In addition, we have currently a 5 fold safety ration based on monkeys only and excluding the ISRs - we should consider whether this should guide us when choosing the next dose.
4. What is the TPP - efficacy as 20mg?
5. Can we patent the frequency?
6. This is also a long term plan, assuming Phase II and Phase III bringing us to 2016 - still relevant?

[redacted]

116. In other words, would a new dosage regimen "still [be] relevant" if Teva could not get the new product to market until 2016, *i.e.,* after market entry of generic Copaxone 20mg? (As it turned out, the different dosing regimen *was* still relevant, because Teva was able to bring

the three-times-weekly dosage to market in January 2014, in advance of generic Copaxone 20mg entering the market.)

117. In a 2008 presentation to the Board of Directors, Teva's executives presented new "Life Cycle Initiatives" that included Copaxone "40mg every other day." However, in a prior communication, a Teva executive had acknowledged that "every other day over once daily **does not represent a significant improvement** in convenience." (emphasis added).

118. By the end of 2008, Teva executives had nonetheless decided to pursue a study to support the 40mg every-other-day dosing regimen. The decision to pursue the study was made despite strong opposition from senior Teva scientists, who argued in a December 24, 2008 email that the study had "no scientific rationale/value." The email further noted that the Life Cycle Management team (the business team responsible for the Copaxone franchise) agreed with the scientists' decision, but believed the study had its "business value":

Dear both,

Please find below the presentation prepared for the discussion in the GA LCM meeting one month ago (the relevant study design can be found in slides 7-9- Option 2- Superiority study GA 32 mg thrice a week vs, placebo, and the appropriate FTE slide can be found in slide 14).

I would like to make it clear that the IR&D management, led by [redacted] are **strongly against the study** since it has no scientific rationale/ value. The IR&D decision was conveyed to the GA LCM team; however, the GA LCM members, though agree with IR&D decision, think that such a study has its business value.

I know from [redacted] that a GIR meeting is planned for 08-09 Jan 09, so I assume that a final decision will be taken then by [redacted]

Please contact me if you need any further clarifications.

All the best

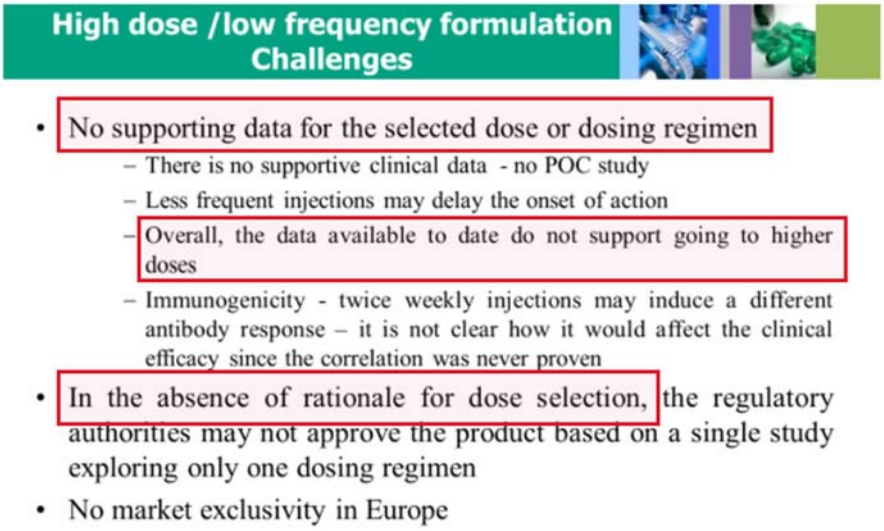
[redacted]

[attachment "GA infrequent injection- Optional scenarios- 19 Nov 08.ppt" deleted by Yifat Shorer/NTA/TEVA/IL]

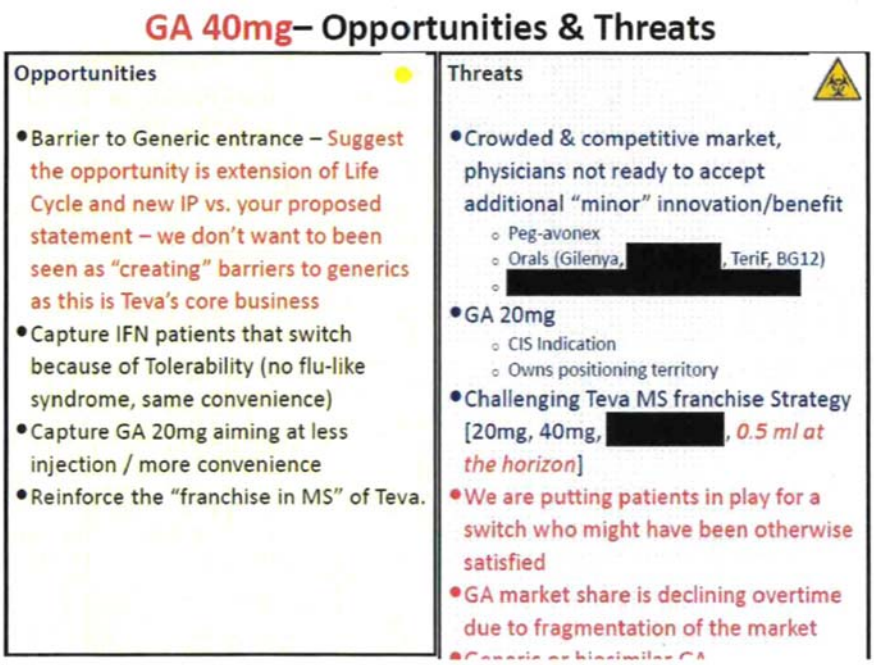
Yossi Gilgun-Sherki, Ph.D.
Global Clinical Leader
Clinical Development Section
Global Innovative R&D
Teva Pharmaceutical Industries, Ltd.
Netanya, Israel

Highly Confidential

119. Despite the lack of a "scientific rationale/value," and despite recognition that the less frequent dosage did "not represent a significant improvement in convenience," Teva continued to pursue the 40mg every-other-day dose. A June 2009 presentation to Teva's then-CEO Shlomo Yanai stressed that "The new formulation must be approved no later than 2014" (*i.e.*, in advance of generic entry) while simultaneous acknowledging that there was "[n]o supporting clinical data for the selected dose or dosing regimen" and that "[o]verall, the data available to date do not support going to higher doses." The presentation cautioned that the "absence of rationale for dose selection" could lead to regulatory denial:



120. However, Teva viewed the 40mg product as an "Opportunit[y]" to create a "Barrier to Generic entrance."



121. A senior Teva executive cautioned that this "Barrier to Generic entrance" language should be removed from the presentation, explaining, "we don't want to be seen as 'creating' barriers to generics as this is Teva's core business."

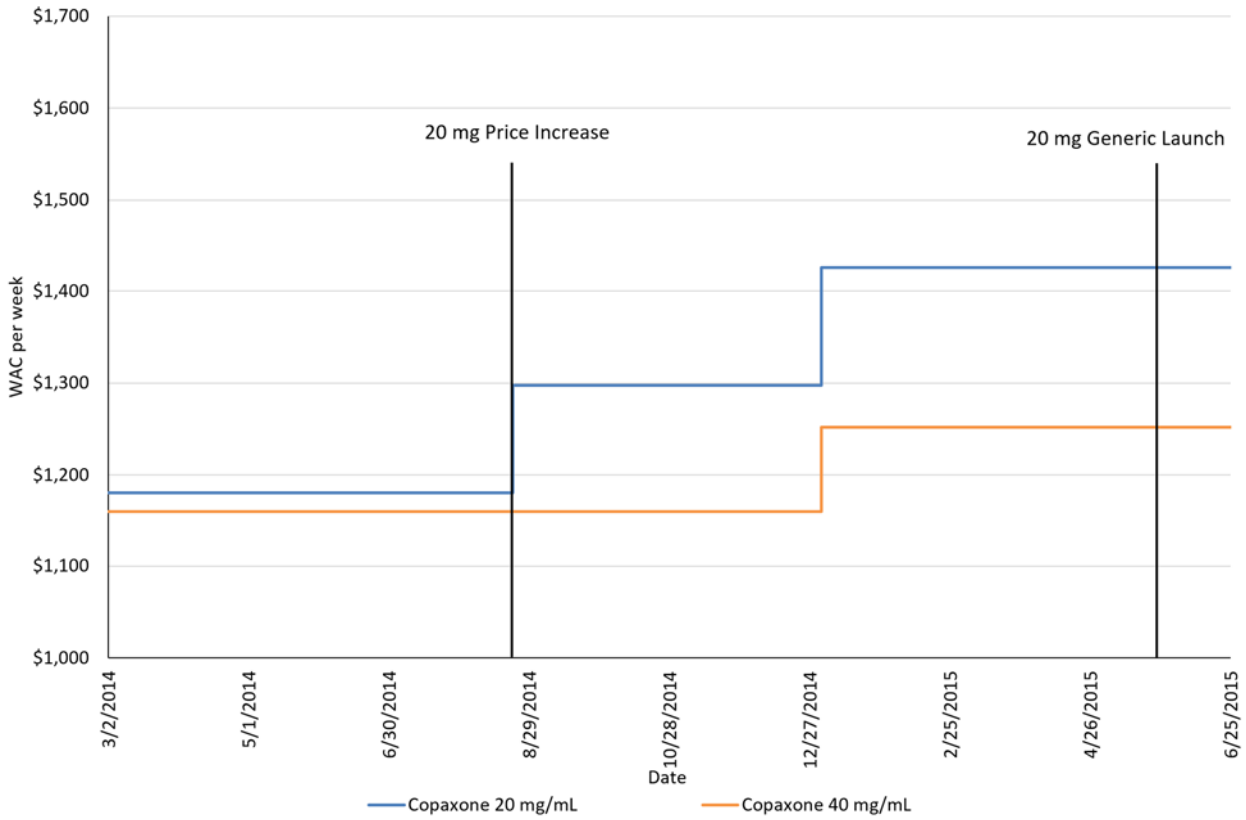
122. On January 28, 2014, Teva received FDA approval for its Copaxone 40mg product and launched the next day. Teva then began converting the market to the 40mg product, for which there was (at that time) no generic competition.

2. Teva leveraged its market power and used coercive tactics to switch the market to Copaxone 40mg to suppress generic competition.

123. Teva took several steps to ensure the "rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014," including: (i) pricing the new 40mg lower than the 20mg product to pressure patients to switch; (ii) planning for the discontinuation of copay assistance for the 20mg product; (iii) causing PBMs to add the 40mg to their formularies by tying rebates; (iv) enlisting PBMs to aggressively lobby doctors to switch their patients to the new dosage; and (v) making Teva's sales forces' bonuses entirely contingent on sales of the 40mg.

124. Teva manipulated pricing in a few ways. First, at the time Teva launched the new 40mg dose, it priced the 40mg product *lower* than the 20mg product. If the 40mg product was, as Teva claimed, "a significant advancement," one would expect Teva to charge *more* (not less) for the superior product. Then, on August 22, 2014, Teva implemented a 9.8% price hike on the 20mg product, causing the older 20mg product to be priced significantly higher than the purportedly superior 40mg product.

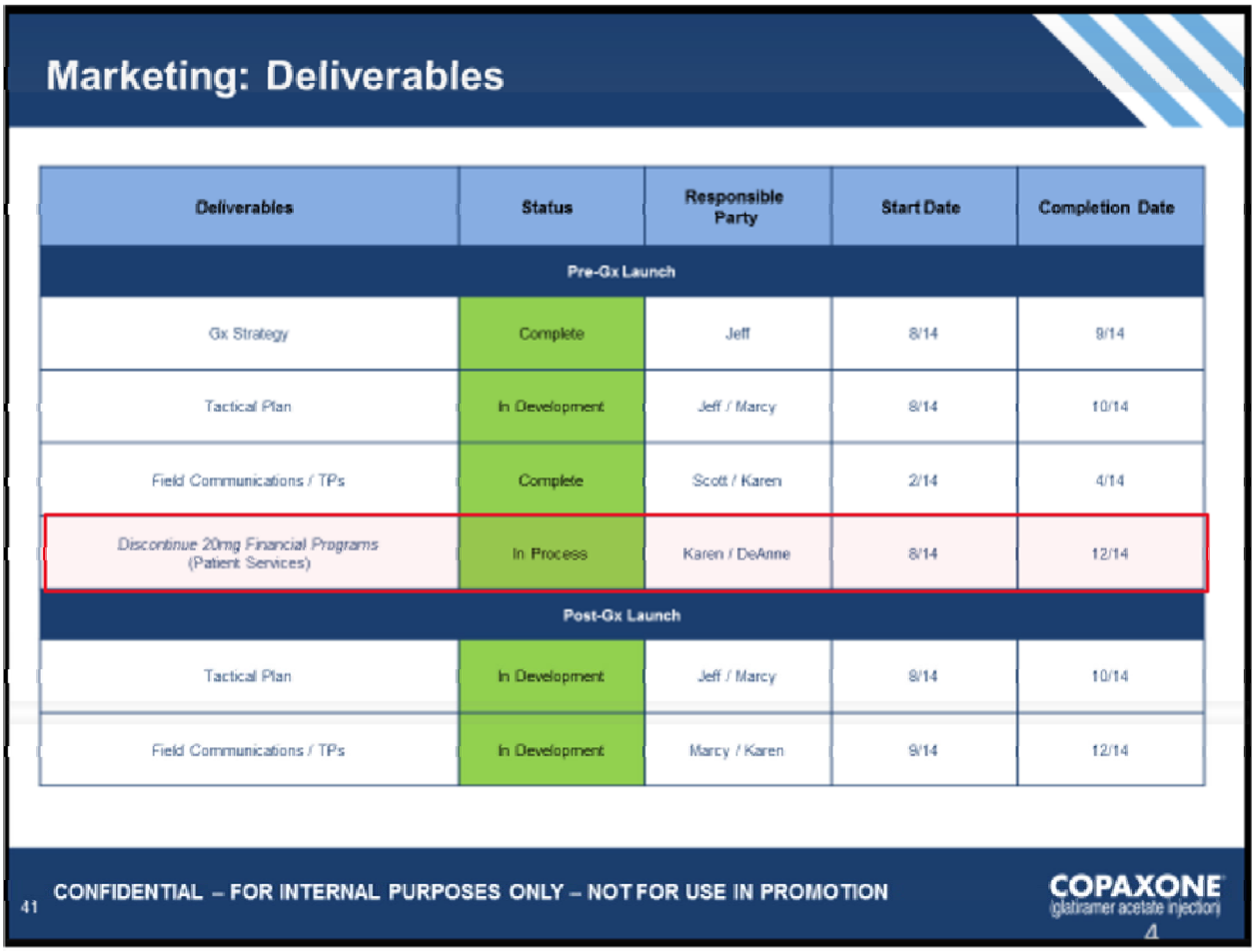
Figure 2: Copaxone Wholesale Acquisition Cost List Price per Week by Strength



Source: ProspectoRx WAC data.

125. A senior Teva executive made clear that the motivation behind these pricing decisions was to prevent generic competition, emphasizing in an internal email that "an important part of [Teva's] generic defense strategy is creating price separation between the 20mg and the 40mg."

126. Internal documents also show that Teva planned to "Discontinue 20mg Financial Programs (Patient Services)" to exert additional pressure on patients to switch to the new dosage.



Marketing: Deliverables

Deliverables	Status	Responsible Party	Start Date	Completion Date
Pre-Gx Launch				
Gx Strategy	Complete	Jeff	8/14	9/14
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	Complete	Scott / Karen	2/14	4/14
Discontinue 20mg Financial Programs (Patient Services)	In Process	Karen / DeAnne	8/14	12/14
Post-Gx Launch				
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	In Development	Marcy / Karen	9/14	12/14

127. In addition, Teva used PBMs to effectuate its product conversion scheme. As a first step, Teva forced PBMs to add the 40mg product to their formularies by conditioning the receipt of any Copaxone 20mg rebates on the PBM's agreement to add the 40mg product to the formulary. The tactic proved effective. Internal Teva emails show that after one PBM lost its 2015 rebates for failing to add the 40mg to its formulary, it got in line the following year and added it.

128. Teva also incentivized PBMs to lobby prescribers directly to switch patients from the 20mg to the 40mg. For example, under its "Copaxone conversion initiative," Humana agreed that it was "committed to converting current Copaxone 20mg patients over to Copaxone 40mg with their physician members" and further represented that, "Humana is contacting the prescribers via fax and phone to make them aware of which patients are still on Copaxone 20mg

and encourage them to switch these patients to Copaxone 40mg." The DOJ and courts have stated that "'conversion' requirements" such as this transform rebate payments into illegal kickbacks.

129. In addition, Teva used its sales force to press prescribers to switch their patients to the 40mg dose to block generic competition. For example, Teva's 2017 "Brand Plan" instructed its sales force to "[e]ncourage physicians to switch patients to [three times weekly] Copaxone 40mg if payers force to generic . . . for daily use." The Brand Plan further stated that sales representatives should push doctors to "[p]rescribe Copaxone DAW [Dispense as Written] for new and existing patients" and urge prescribers to "[e]ncourage their patients to accept only branded Copaxone."

130. To further incentivize its sales force to convert patients to 40mg Copaxone, Teva made their bonuses entirely dependent on 40mg sales. As one internal document put it: "The sales force is only paid on 40mg sales."

131. On June 18, 2015, Sandoz began selling generic Copaxone 20mg. However, because of Teva's coercive tactics, the vast majority of the market had been converted to the 40mg dosage, foreclosing competition from Sandoz's generic product. More specifically, by the end of 2015, Teva had converted approximately 77% of Copaxone patients to the 40mg product. In June 2016, approximately one year following the market entry of the generic 20mg product, Teva's General Manager of Neuroscience John Hassler circulated a presentation boasting that, "The strategy of switching patients to 40mg version of the medicine is continuing to be successful and reduce the impact of generic competition." By the end of 2016, Teva had succeeded in converting 84% of the market to the 40mg dosage.

132. Teva's product switch substantially foreclosed generic competition because it denied generic manufacturers a fair opportunity to compete using state substitution laws. It is

widely recognized that generic substitution is the cost-efficient means for generic manufacturers to compete, which is due in part to the disconnect that exists between the person selecting the patient's treatment and the person or entity who ultimately pays for that drug. As a result, the market forces that would ordinarily allow patients and other payors to consider price when making a product selection are absent. Moreover, a patient whose prescription had been converted to the 40mg product cannot simply ask that the pharmacist fill the prescription with generic 20mg; the two products are not A-rated equivalents and therefore the 20mg product may not be substituted for the 40mg.

133. Teva's coercive campaign to switch patients to the 40mg effectively eliminated the free choice of consumers, forcing buyers to purchase brand Copaxone 40mg despite the availability of more affordable generic Copaxone.

134. Moreover, Teva's product switch entailed moving its *existing* patients to a product that Teva priced *lower* than the old product. Teva's switch scheme therefore does not make economic sense, other than as a tool to impair generic competition. Teva's conduct also cannot be explained away as a simple effort to "win" consumers to a new product with discounts. Teva did not "win" consumers to the 40mg. It forcibly switched patients to the 40mg through a coercive campaign and then manipulated pricing to discourage patients and prescribers from reverting to the old product, which faced automatic generic substitution.

135. Teva's coercive product switch cost the United States healthcare system between $4.3 billion and $6.5 billion in additional expenditures between 2015 and 2017.

F. Teva entered into exclusionary agreements to impede generic competition.

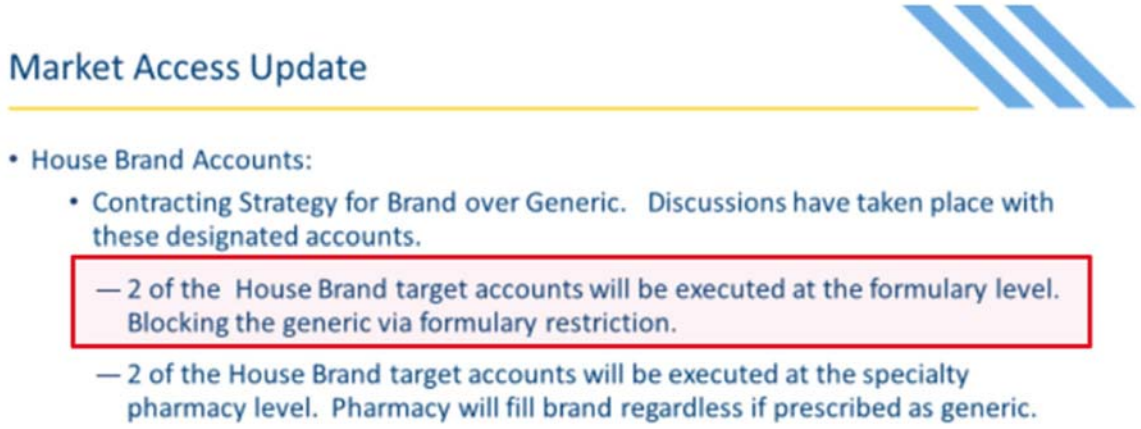
136. Although its product switch scheme was exceedingly effective at suppressing generic competition, Teva did not stop there. Internal Teva documents reveal that Teva entered into exclusionary agreements with PBMs that effectively barred generic Copaxone from being

dispensed. These exclusionary agreements severely restricted market access for generic Copaxone and substantially lessened competition, as Teva intended. Exclusionary agreements of this nature are particularly concerning where, as here, they are imposed by a monopolist. Teva entered into these exclusionary contracts in furtherance of its overarching scheme to extend its monopoly and suppress generic competition.

137. The Staff Report and certain documents cited in the Report suggest that one means Teva used to induce PBMs to accept the exclusionary contracts was by paying rebates. While those rebates may have benefited the specific recipients of the rebates, those recipients did not include Plaintiffs or their assignors, which were forced to buy branded Copaxone rather than less expensive generic Copaxone because of Teva's exclusionary scheme. As a result of Teva's exclusionary conduct, generic manufacturers were effectively foreclosed from the market, causing harm to competition and to Plaintiffs. Teva's exclusionary contracts were part of an overarching scheme to suppress generic competition.

1. Teva's exclusionary agreements with PBMs prevented patients' insurance plans from covering generic Copaxone.

138. In early 2017, Mylan was poised to enter the market with the second generic Copaxone 20mg product and the first generic Copaxone 40mg product. In response, Teva had begun to implement a two-part "Contracting Strategy for Brand over Generic." First, with respect to PBMs, Teva entered into exclusionary agreements that "Block[ed] the generic via formulary restriction."

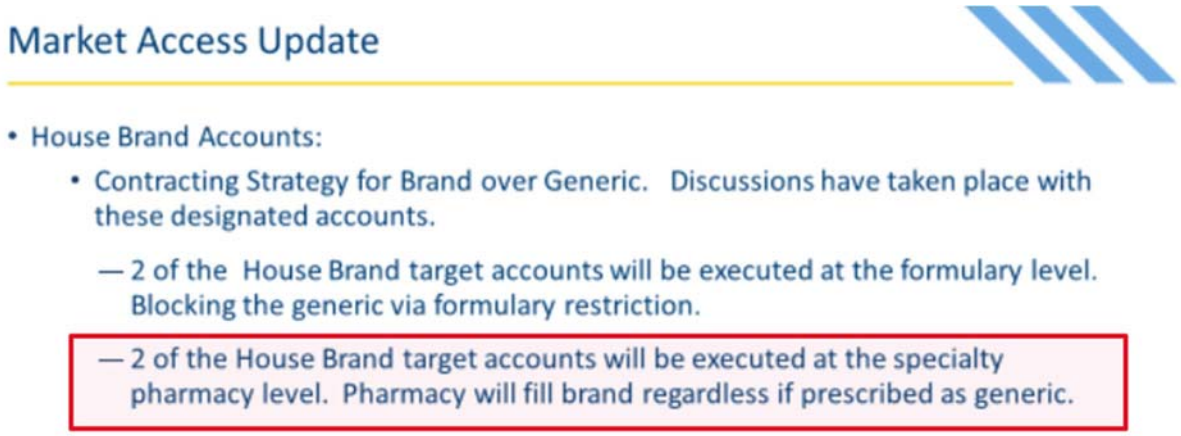


139. "Blocking" generic Copaxone "via formulary restriction" meant that generic Copaxone would be excluded from PBM formularies and therefore the cost of the generic drug would not be covered by health plans. As a result, patients receiving generic Copaxone would be forced to bear the full cost of generic Copaxone, while brand Copaxone continued to be listed on formularies and therefore covered by insurance. By cutting off generic Copaxone from formularies (and therefore from insurance coverage), Teva used its dominant market position to severely restrict patient access to generic Copaxone, substantially lessening competition.

140. Moreover, there is no cognizable, non-pretextual, procompetitive justification for Teva's exclusionary conduct that would outweigh its harmful effects. The exclusion of generic Copaxone from the PBM's formulary is at odds with the very purpose behind the formulary, *i.e.*, to provide high quality care using the most cost-effective options. A drug that has been approved by the FDA as an AP-rated generic is therapeutically equivalent to the brand drug. The only material difference between the generic and the brand is the substantially lower cost of the generic product.

2. Teva's exclusionary agreements with PBM-associated specialty pharmacies precluded the pharmacies from dispensing generic Copaxone at all.

141. Teva took an even more direct approach to excluding competition at the pharmacy level. In return for large payments, certain specialty pharmacies associated with PBMs agreed that they would "fill brand regardless if prescribed as generic."



142. Teva's Executive Vice President for North America confirmed that the illegal agreement was indeed that blatant, stating in an internal email, "**[the specialty pharmacy] only ships brand Copaxone no matter how it is written or what the formulary states.**"

143. He further explained, "Because [the PBM] is getting an additional rebate to fill all 'glatiramer' or Copaxone scripts with Copaxone . . . if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside**."**

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...

Best regards,

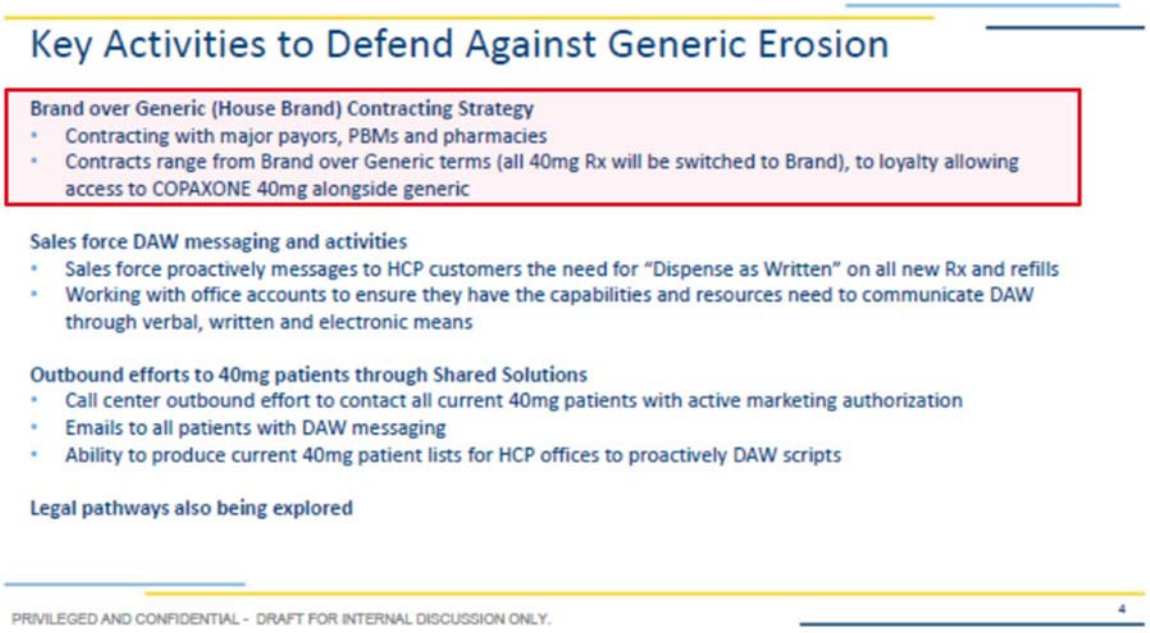
<image001.png> Brendan P. O'Grady EVP and Head of North America
Highly Confidential

<image002.png>

144. In other words, Teva was paying certain specialty pharmacies to ignore doctors' orders and legally imposed generic substitution requirements and instead always ship brand Copaxone no matter what. In addition to violating the antitrust laws prohibiting exclusionary conduct, these payments to pharmacies violated the federal Anti-Kickback Statute. More specifically, the DOJ has made clear that where a drug manufacturer makes payments to a pharmacy to increase utilization of the manufacturers' drug, regardless of the label used, the payment will not fall within the safe harbor provision of the Anti- Kickback Statue, a federal statute that prohibits any entity from soliciting or receiving any remuneration "in return for purchasing . . . or recommending purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §1320a- 7b(b)(1).

145. The Teva executive concluded the email by stating that the arrangement was a "Win-win for all . . ." It was a "win" for Teva because it unlawfully extended Teva's monopoly and earned it billions of dollars in illegal profits; and it was a "win" for the PBM-owned specialty pharmacies that received the illegal kickbacks. However, it was a decided loss for generic competitors, which were foreclosed by Teva's exclusionary conduct, and for drug purchasers, who were forced to purchase more expensive branded Copaxone despite the availability of less expensive generic Copaxone.

146. An internal October 2017 presentation to Teva's Board of Directors makes clear that Teva's "Brand over Generic (House Brand) Contracting Strategy" was undertaken not to compete, but to "Defend Against Generic Erosion":



147. Teva monitored and reported internally on the "success" of its scheme to suppress competition and frustrate generic uptake. For example, on October 26, 2017, Teva Neuroscience General Manager John Hassler reported to Teva's CEO Larry Downey that "Two weeks post generic approval, the team has had early success in achieving key Brand over Generic goals." Teva executives cautioned that the agreements were confidential and should not be shared even within the company.

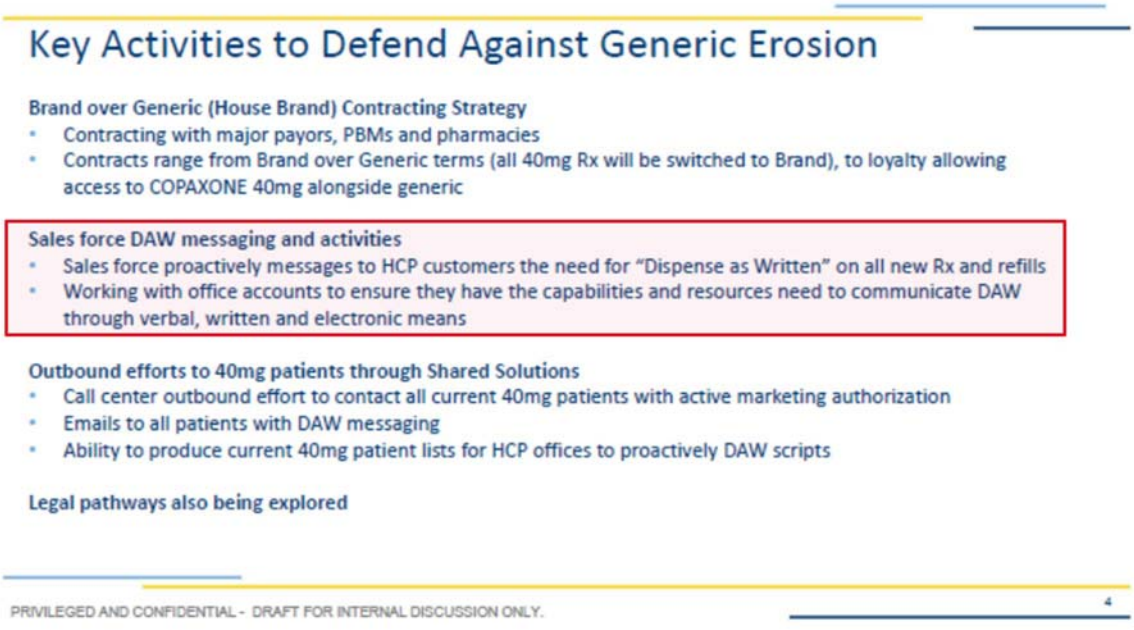
G. Teva engaged in an aggressive "Dispense as Written" campaign that depended in part on spreading misinformation about generic Copaxone.

148. Automatic generic substitution cannot occur if the prescriber writes "Dispense as Written," "DAW" or its equivalent on the prescription. When the physician elects to include this instruction in the prescription, the pharmacist is not permitted to substitute a generic drug for

the brand product, even though the generic drug has been approved by the FDA as therapeutically equivalent to the brand.

149. On October 3, 2017, Mylan received final FDA approval for its generic Copaxone 40mg and 20mg products and launched the following day. In response, Teva ramped up its "DAW" campaign, which included making untrue and misleading statements to doctors and patients regarding the efficacy, safety, and substitutability of generic Copaxone.

150. Teva's aggressive "Dispense as Written" campaign was deployed in part through Teva's sales force, which was tasked with (among other things) "proactively messaging [Health Care Provider ("HCP")] customers the need for 'Dispense as Written' on all new Rx and refills":



151. Because generic Copaxone is an FDA approved, therapeutically equivalent generic, there would be no valid scientific basis for a claim that there was a "need" for health care providers to write "'Dispense as Written' on all new Rx and refills."

152. A lawsuit filed by drug manufacturer Mylan against Teva revealed that Teva "[d]rafted and propagated a playbook of false and misleading statements designed to dissuade

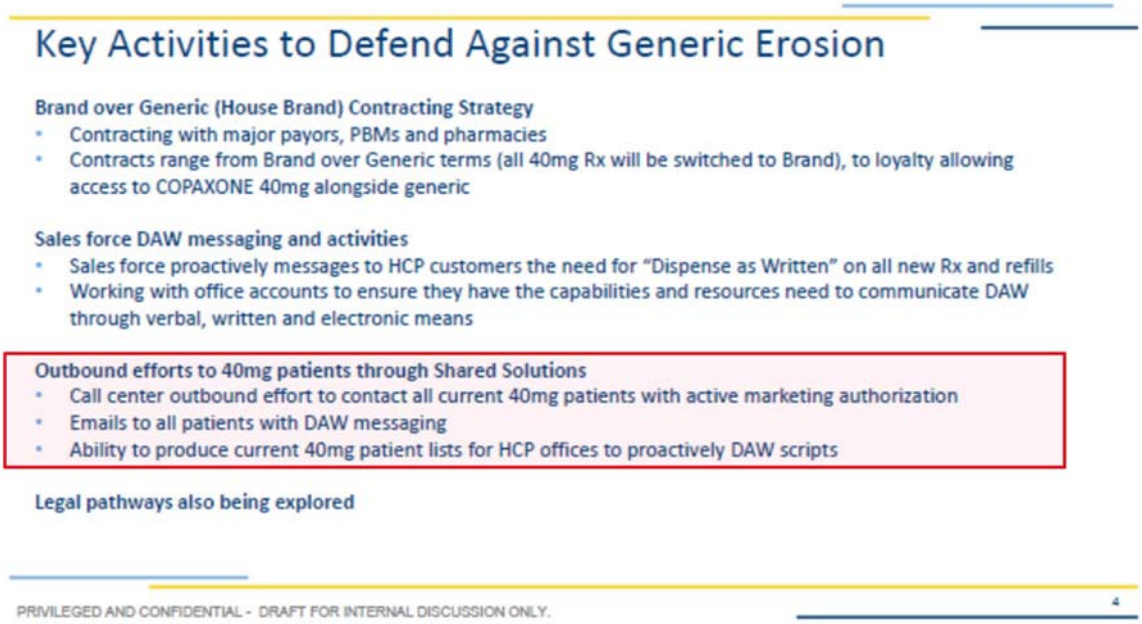
health care providers and MS patients from accepting generic [Copaxone] as part of a campaign to persuade doctors to prescribe, and patients to request, branded Copaxone 'dispense as written.'"

153. Teva persuaded doctors to write "Dispense as Written" on all Copaxone prescriptions in part by asserting, without any scientific basis, that generic Copaxone was only 80% to 85% as effective as branded Copaxone. Teva also wrongly asserted that Mylan did not offer injection training or nursing support to patients. Teva's misinformation campaign was pernicious, causing Mylan to go to unprecedented lengths to correct the misinformation, only to have providers refuse to speak to Mylan representatives about the issue:

> These false, misleading, and deceptive statements have caused health care providers and patients to avoid Mylan's generic GA product, impeded automatic substitution, and substantially reduced Mylan's sales. While Mylan, as a generic manufacturer, does not ordinarily market its generic drugs through sales representatives, it tried to correct Teva's misrepresentations by having company representatives communicate with health care providers. However, Mylan's efforts to revive its reputation were thwarted because a large number of providers already believed Teva's lies and refused to even talk to the Mylan representatives or argued with them using the arguments they heard from Teva.

154. Although they are sophisticated decisionmakers, doctors rely on drug manufacturers for information; and it is reasonable for a prescriber to expect that drug manufacturers will refrain from knowingly making representations that are objectively untrue. Here, Teva asserted, without any basis whatsoever, that the generic product was only 80% to 85% as effective as the brand product and that the generic product presented grave safety concerns (among other untrue statements). Assertions such as these, which appear to be fact-based but which are not, are difficult if not impossible to neutralize, as Mylan learned when it attempted to counter Teva's misinformation campaign.

155. Teva also used its patient services program, referred to as Shared Solutions, to bombard patients with its "Dispense as Written" campaign, using a call center to "contact all 40mg patients with active marketing authorization" and sending emails to "all patients with DAW messaging." According to Mylan, Teva's Shared Solutions personnel communicated misinformation directly to MS patients about generic Copaxone, including wrongly asserting that generic Copaxone manufacturers did not offer training and nursing support and did not offer financial assistance. Teva also used Shared Solutions to "produce current 40mg patient lists" to provide to doctors' offices, so that they could "proactively DAW scripts."



Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy
- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities
- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions
- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

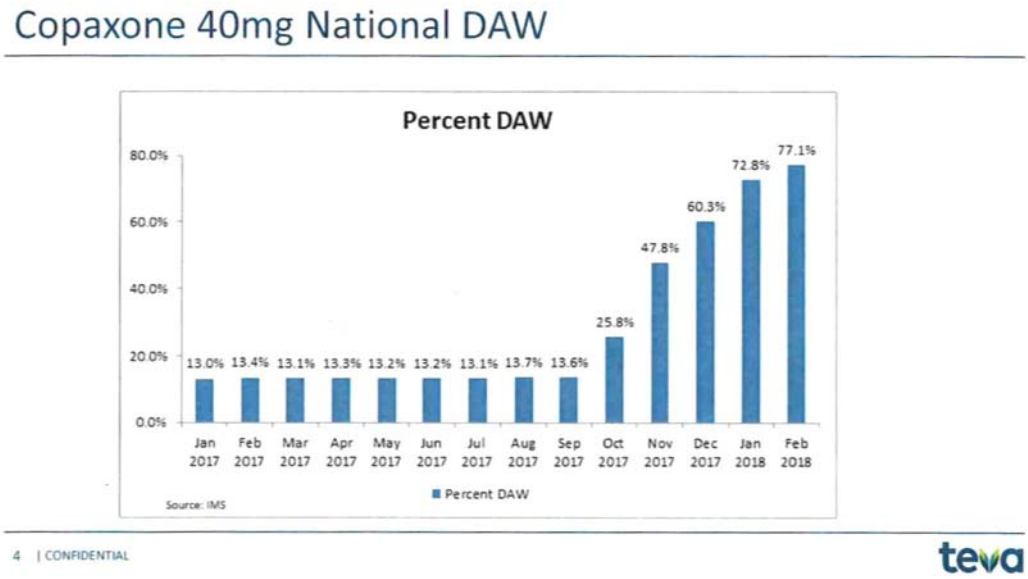
PRIVILEGED AND CONFIDENTIAL - DRAFT FOR INTERNAL DISCUSSION ONLY.

4

156. This is not a case where Teva simply boasted about the superiority of its product in comparison to generic Copaxone. Rather, Teva made baseless, demonstrably untrue statements to patients, who necessarily rely on the information that drug manufacturers provide about their medications.

157. Rather than compete on the merits, Teva relied on defamation of generic Copaxone to advance its DAW campaign with the purpose of preventing generic competition.

Teva's deceptive DAW campaign had its intended effect. According to internal reports, the rate at which "Dispense as Written" was noted on Copaxone 40mg prescriptions rocketed from approximately 13% to more than 77% in the four months following the launch of generic Copaxone 40mg."



158. This means that within months of the launch of generic Copaxone 40mg, Teva had locked up more than three-quarters of Copaxone 40mg prescriptions through its deceptive DAW campaign, such that generic Copaxone 40mg could not be substituted. In contrast, generic market share after one year is typically 80% or greater.

159. The Dispense as Written campaign was extremely lucrative for Teva. In August 2018, Teva's Executive Vice President for North America Brendan O'Grady remarked that the "DAW campaign combined with the legacy and house brand access strategy has paid great dividends." He continued: "I want to exceed $1.5 [billion] for the year on Copaxone. We did $900 [million] in [the first half of 2018] so we only need to do $50 [million+] in [the second half

of 2018] to accomplish this goal." Teva succeeded in hitting this goal. In 2018, Teva's net revenue on Copaxone topped $1.6 billion, despite the availability of multiple generic Copaxone products, at least one of which had been on the market for more than three years.

160. The Dispense as Written campaign is ongoing and continues to harm generic competition.

H. Teva paid illegal kickbacks and made other payments to drive up brand Copaxone sales.

161. During the relevant time period, Teva subsidized Copaxone patient out-of-pocket costs and offered other free services, which induced patients to purchase brand Copaxone instead of more cost-effective, therapeutically equivalent generic Copaxone.

162. Teva provided patient assistance through three primary channels. First, for Medicare patients, Teva provided cash donations to third party foundations to cover the patients' out-of- pocket cost for brand Copaxone. Second, for patients with commercial insurance, Teva offered the "Copaxone Co-Pay Solutions" program. Under this program, Teva covered the co-pay amount that patients would otherwise owe on their brand Copaxone purchases. Third, Teva offered patient services, such as free injection devices, to promote patient use of brand Copaxone and provide a forum for connecting patients with the financial aspects of Teva's patient assistance programs.

163. Teva characterized the kickbacks and other payments as, *e.g.,* "charitable cash contributions" and "donations" that justified Teva's price increases. In truth, Teva's payments were made with the purpose of driving up brand Copaxone sales, which increased Teva's revenues and suppressed generic competition.

164. Senior Teva management was aware of these payments. Indeed, some of the larger payments required approval from senior Teva executives, including Teva CEO Erez Vigodman:

Approval Authority Levels
$0.5M Sr. Director
$1M VP
$5M SVP (Larry Downey in the past)
$15M TEC members (Rob Koremans)
$25M CFO (Eyal Desheh)
>$25M CEO (Erez Vigodman)

1. Teva violated the Anti-Kickback Statute.

165. The Anti-Kickback Statute, 42 U.S.C. § 13320a-7b(b), prohibits drug manufacturers from subsidizing the out-of-pocket costs of Medicare and Medicaid patients. Under the statute, a drug manufacturer is prohibited from using charities to funnel money to patients with the intent of driving up the drug manufacturer's sales. Guidance provided by the Department of Health and Human Services explains that "pharmaceutical manufacturers can donate to *bona fide* independent charity [patient assistant programs]" where "appropriate safeguards exist." However, "the independent [patient assistance program] must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices."

166. On August 19, 2020, the DOJ filed a lawsuit alleging that Teva paid illegal copay subsidies that violated the Anti-Kickback Statute. Beginning in 2006, Teva referred Medicare and Medicare-eligible patients who were taking Copaxone to Advance Care Scripts, Inc. ("ACS"), a specialty pharmacy, to assist the patients with obtaining Medicare Part D coverage and copay assistance. Concurrently, Teva was making cash donations to the Chronic Disease Fund ("CDF") (and later to The Assistance Fund ("TAF")), which operated a fund for MS patients intended to help cover the copay costs associated with various MS medications.

167. Teva coordinated the amount and timing of its donations to CDF and TAF to increase the likelihood that the payments would cover brand Copaxone copays only, thereby driving up brand Copaxone sales. Specifically, Teva worked closely with ACS (and later

AssistRx) to calculate the exact amount needed to cover the Copaxone copayments for a specific number of patients. Teva then timed its donations to CDF and TAF to coincide with ACS's submission of a batch of patient applications to CDF and TAF. These two actions (*i.e.,* Teva transmitting payment and ACS submitting a batch of patient assistance applications) were also timed to occur when CDF's and TAF's MS funds had zero dollars available, thus maximizing the chance that Teva's donations would be funneled directly to Copaxone copays.

168. According to Edward Hensley, ACS's founder, Teva refused to provide funding to at least one charitable foundation due to its failure to limit funds to Copaxone copays only. Mr. Hensley attested that Denise Lynch, who served as Teva's Director of Customer Resources and later as Teva's Vice President of Patient Services, told Mr. Hensley that "she would not authorize donations to Patient Services Inc. ("PSI") because PSI had 'burned' her with respect to a prior donation," by which she meant that Teva's donation to PSI "had not been passed through to Copaxone patients, but rather had been used to cover the co-pays of patients who had been prescribed competitor MS drugs."

169. Mr. Hensley further attested that he "understood that Teva was purposefully utilizing ACS and structuring its donations to CDF in a manner that essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications."

170. Subsequently, when TAF took over the role of CDF, Mr. Henlsey "made sure that Ms. Lynch understood that Teva effectively would be able to use TAF as it had CDF: essentially, as a 'pass-through' donation vehicle to get Teva monies into the hands of Copaxone patients."

171. From 2006-2015, Teva paid more than $328 million in illegal kickbacks to drive up brand Copaxone sales. Information submitted to the House Committee indicates that Teva continued making these donations into 2018.

172. Teva knew that its donations to CDF and TAF increased Medicare claims for brand Copaxone and increased Teva's revenue. Internally, Teva characterized its patient assistance programs as an "investment" and tracked the specific "return on investment" ("ROI") associated with these programs, which was substantial. With respect to Teva's "Medicare Financial Assistance" program, the Staff Report estimated that the ROI was 200%.

173. Teva's illegal kickbacks drove up brand Copaxone sales and suppressed generic competition. Plaintiffs were harmed by having to purchase more expensive brand Copaxone instead of less expensive generic Copaxone.

2. Teva's commercial copay assistance program induced patients to remain on brand Copaxone rather than switching to more affordable generic Copaxone.

174. Teva also had a copay assistance program for commercially insured patients, which similarly entailed Teva making payments to cover patient copays to drive brand Copaxone sales.

175. In 2007, CDF began administering Teva's Copaxone Private Copay Assistance Program.

From: Melissa Ayles [mailto:MAyles@cdfund.org]
Sent: Monday, November 05, 2007 10:14 AM
To: admin@cdfund.org
Subject: CD Fund now administering Copaxone Private Copay Assistance Program
Importance: High

Dear Participating Specialty Pharmacy,

Please be advised that effective November 1, 2007, Chronic Disease Fund began administering the Copaxone Private Copay Assistance Program. Should you identify privately insured patients in need of copay assistance, please refer them directly to Shared Solutions and identify yourself as making the referral. Shared Solutions will provide a daily feed of referrals to us with the pharmacy assignment included and we will, in turn, refer the patient back to you via the normal daily referral process. Please do not submit privately insured Copaxone patients to us via the daily referral process.

Please call me if you have any questions.

Best Regards,

Melissa Ayles
Senior Director, Partner Relations
Chronic Disease Fund, A Non-Profit Organization
10880 John W. Elliott Drive, Suite 400
Frisco, TX 75034

Direct: (214) 975-5180
Fax: (214) 975-1114
Cell: (972) 998-0837

176. As with its Medicare copay assistance program, Teva's return on investment for its commercial copay assistance program was substantial. An internal report revealed that in 2015, Teva collected $148.2 million in net revenue from its $68.4 million expenditures on Teva's co-pay program for commercial patients.

177. Teva's Executive V.P. for North America touted internally that even if an insurer were to move brand Copaxone to the non-preferred tier of its formulary, the change "means little because we buy the patients [sic] copay down to zero anyway."

178. As a result of its commercial copay assistance program, Teva retained patients on brand Copaxone despite the availability of more cost effective generic Copaxone, causing Plaintiffs to purchase more brand Copaxone than they otherwise would have.

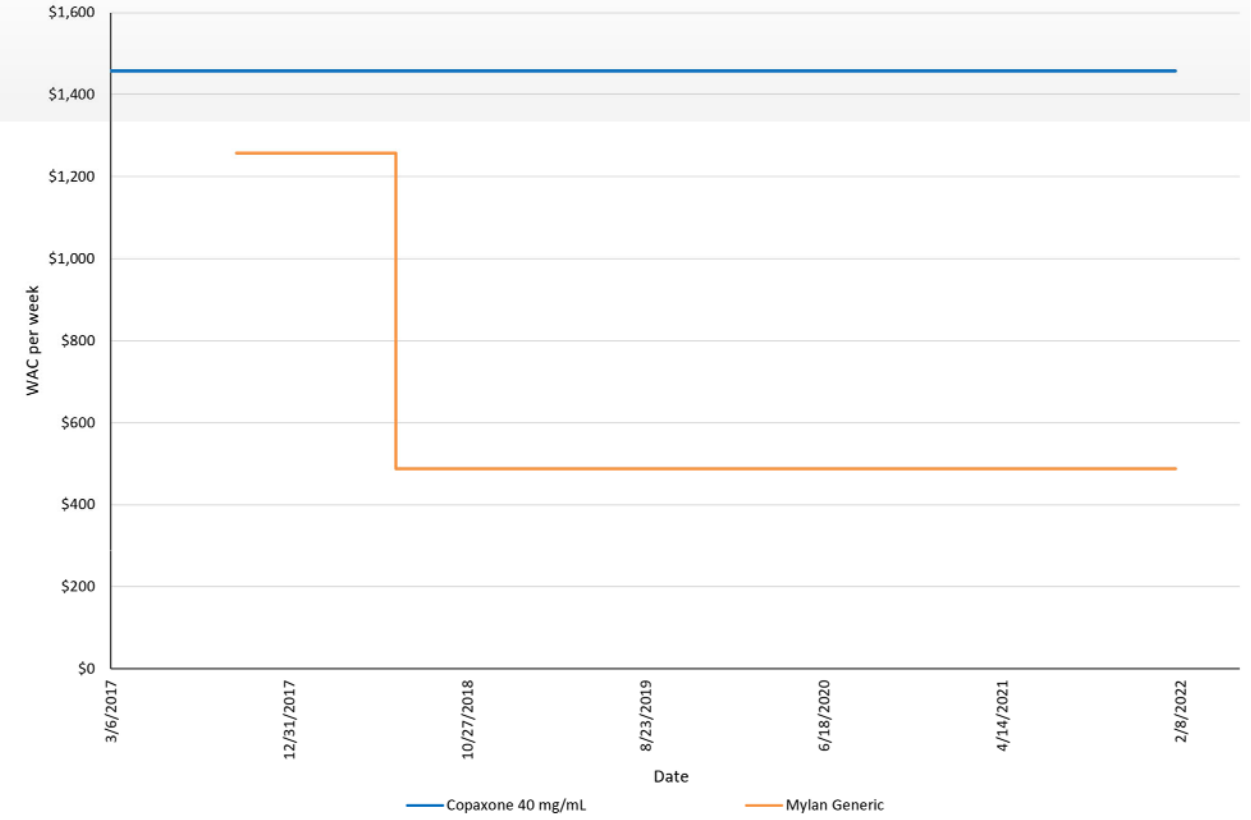
I. Teva has succeeded in suppressing generic competition.

179. The combined effect of Teva's multifaceted monopolization scheme has been to substantially foreclose generic competition and unlawfully maintain Teva's dominant market

share, for years. Despite the launch of several generic versions of Copaxone, Teva continues to dominate the market. Taken as a whole, the scheme has harmed Plaintiffs and their assignors by causing them to pay overcharges on their purchases of Copaxone.

180. Teva was so effective at blocking generic Copaxone that even a 60% price cut by Mylan had only a muted impact on Teva's market share. Specifically, in July 2018, Mylan cut its price by more than half. (*See* Figure 3). Yet, as of June 2019, Teva still held more than 64% of the market.

Figure 3: Copaxone and Mylan Generic 40 mg Price per Week



Source: ProspectoRx WAC data.

181. In contrast, a typical generic entering a market will cause the corresponding brand market share to fall to 20% or less within a year.

182. Teva has openly boasted about the effectiveness of its scheme to suppress generic competition. For example, in November 2019, Teva touted to investors that, despite the years-long availability of more cost-effective generic Copaxone, Teva still held 63% of the market.

VI. MARKET POWER AND RELEVANT MARKET

183. At all relevant times, Teva had substantial market power in the market for Copaxone and its AP-rated generic equivalents. Teva had the power to maintain Copaxone prices at supracompetitive levels without losing sufficient sales to other products to make the supracompetitive prices unprofitable.

184. A significant, non-transitory increase in the price of brand Copaxone, above the competitive level, did not cause a significant loss of sales to any product other than AP-rated versions of Copaxone. At competitive prices, brand Copaxone does not exhibit significant, positive cross-elasticity of demand with any product or treatment for RRMS other than AP-rated generic versions of Copaxone.

185. Direct evidence of Teva's market power includes the following: (a) from 2013 to 2018, the per-unit manufacturing cost for Copaxone was less than 3% of the net price of the drug, *i.e.*, the price after adjusting for rebates and discounts; (b) Teva never lost Copaxone sales in response to pricing of other brand or generic drugs, except for less expensive AP-rated generic Copaxone; (c) Teva never lowered the price of Copaxone in response to the entry or pricing of other brand or generic drugs; and (d) from 2006 to 2015, prior to generic entry, Defendants profitably raised the price of Copaxone 20mg by approximately 350%.

186. Branded Copaxone is therapeutically differentiated from all RRMS products other than AP-rated generic versions of Copaxone. No such product is an economic substitute for branded Copaxone—*i.e.*, a product that has constrained Teva from pricing Copaxone above the competitive level because doing so would cause purchasers to switch to those products in

numbers that would make the higher prices unprofitable. In fact, Teva has continually increased the prices for Copaxone over the years, even when new RRMS injectable disease-modifying therapies were approved by the FDA.

187. To the extent that Plaintiffs are required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant antitrust product market is the market for Copaxone and its AP-rated generic equivalents.

188. At all relevant times, Teva was protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. Teva's unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Teva's higher prices or reduced output.

189. The relevant geographic market is the United States.

190. Teva's market share in the relevant market was 100% until Sandoz's generic entry in June 2015. Even after generic entry, Teva has maintained and continues to maintain a majority of the glatiramer acetate market for a significant period of time.

VII. INTERSTATE COMMERCE

191. The drugs at issue in this case were manufactured and sold in interstate commerce, and the unlawful conduct alleged herein occurred in, and had a substantial effect on, interstate commerce.

VIII. ANTITRUST IMPACT

192. During the relevant time period, Plaintiffs' assignors purchased substantial quantities of Copaxone directly from Teva. Teva's unlawful scheme, taken as a whole, has forced Plaintiffs and their assignors to purchase more units of branded Copaxone at monopoly prices and fewer units of less expensive generic equivalents, resulting in overcharges. Plaintiffs are not required to prove that each and every individual element of Teva's unlawful scheme to monopolize caused injury to Plaintiffs, only that the scheme as a whole did so.

193. Plaintiffs have sustained and will continue to sustain substantial loss and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

194. Teva's unlawful scheme remains in place and Plaintiffs' injuries are ongoing. Plaintiffs (and their assignors) will continue to pay overcharges on their purchases of Copaxone for months or years into the future. Thus, Defendants' conduct threatens continuing loss and damage to Plaintiffs unless enjoined by this Court.

IX. CLAIM ACCRUAL AND TOLLING

195. By virtue of their assignments, Plaintiffs are members of the putative class of direct purchasers sought to be certified in a case pending in the District of New Jersey: *FWK Holdings, LLC et al. v. Teva Pharm. Indus., Ltd.*, Case No. 2:22-cv-1232-JSN-JSA (ECF Doc. 2, filed March 8, 2022). The limitations period applicable to Plaintiffs' claims has been tolled since the filing of that case on March 8, 2022. Moreover, under the separate accrual rule, a separate cause of action accrued to Plaintiffs' assignors each time they purchased Copaxone (or generic Copaxone) at a price higher than the price they would have paid absent Teva's unlawful conduct, and those causes of action have been assigned to Plaintiffs. Thus, without the benefit of any additional tolling doctrine, Plaintiffs are entitled to recover overcharges paid on purchases of

Copaxone or generic Copaxone beginning four years prior to March 8, 2022, *i.e.*, beginning on March 9, 2018.

196. Plaintiffs' claims for overcharges based on purchases prior to March 9, 2018 are also timely because Teva fraudulently concealed its unlawful conduct, and Plaintiffs did not and could not have discovered Teva's antitrust violations by the exercise of reasonable diligence prior to the publication of the Staff Report on September 30, 2020. The doctrine of fraudulent concealment applies because (a) Teva affirmatively concealed its violation of the antitrust laws, (b) Plaintiffs remained in ignorance of their claim until approximately September 30, 2020, and (c) Plaintiffs' ignorance was not attributable to lack of diligence on their part.

197. Plaintiffs could not have known that Teva was entering into exclusionary agreements with PBMs and certain of their associated specialty pharmacies to bar generic Copaxone until the House Committee published the Staff Report on September 30, 2020. Teva took steps to keep these anticompetitive agreements secret. This included senior Teva executives warning subordinates that the exclusionary agreements with PBMs and certain of their associated specialty pharmacies should not be shared even internally with other Teva employees due to their "confidential nature." Moreover, internal communications discussing the exclusionary contracts were prominently stamped with the admonition: "DO NOT COPY. DO NOT DISTRIBUTE."

198. Plaintiffs also could not have known, prior to publication of the Staff Report, that Teva's pursuit of the new 40mg product was motivated by a desire to create a "Barrier to Generic entrance" and that the effort was opposed by senior Teva scientists. Nor could Plaintiffs have known that Teva was coercing PBMs into adding Copaxone 40mg to their formularies through rebate tying and that Teva was enlisting PBMs to aggressively lobby doctors to convert their patients to the new 40mg product.

199. Teva also gave pretextual justifications for its Copaxone pricing, which in truth was driven by a desire to force patients to switch from the 20mg to the 40mg product. For example, a set of October 2016 talking points "Intended for use by Copaxone Communications, [Investor Relations] and Teva Leadership" instructed that, if asked about why Copaxone 40mg was priced lower than the 20mg product, the speaker was to respond that "COPAXONE 40m/mL offers a strong value proposition when compared to [Sandoz's generic Copaxone 20mg product] Glatopa." Teva also claimed that its Copaxone pricing was due, not to its illegal monopoly, but to its ongoing R&D efforts. In truth, as the House Committee reported, "Teva was unable to identify any R&D expenditures related to Copaxone after 2015." Through these and other statements, Teva concealed the truth that its Copaxone pricing was the result of, and in furtherance of, its illegal scheme to suppress generic competition.

200. Similarly, Plaintiffs could not have known about Teva's "Dispense as Written" campaign until the issuance of the Staff Report. And only subsequently, when Mylan filed its lawsuit against Teva on June 29, 2021, did it come to light that Teva's "Dispense as Written" campaign was fueled by misrepresentations regarding generic Copaxone, including untrue statements about the efficacy of the generic products.

201. One aspect of Teva's overarching monopolization scheme, Teva's payment of illegal kickbacks to drive up brand sales, became public some time prior to the publication of the September 30, 2020 Staff Report. Specifically, on November 20, 2019, the DOJ announced that it had entered into a settlement agreement with TAF regarding its role in the illegal kickback scheme and, on August 18, 2020, the DOJ filed a lawsuit against Teva arising out of this misconduct. Teva and its co-conspirators had taken steps to conceal that Teva's donations were not legitimate charitable donations to aid multiple sclerosis patients, but in fact were illegal kickbacks calculated, coordinated, and timed to cover Copaxone copays only.

202. However, the full scope of Teva's scheme did not become publicly known until issuance of the Staff Report on September 30, 2020. Notably, the Staff Report was based on the House Committee's review of over 300,000 pages of internal, nonpublic documents and communications produced by Teva to the Committee in response to a formal request. Similarly, the Mylan complaint filed in June 2021 set forth information that could not have been known by Plaintiffs prior to the filing of that action.

203. Teva's illegal monopolization scheme was also inherently self-concealing because, as Teva knew, disclosure of the scheme would have exposed it to civil liability and governmental enforcement actions, as in fact occurred when the scheme came to light.

204. As a result of Teva's fraudulent concealment, the four-year statute of limitations applicable to Plaintiffs' claims was tolled at all relevant times and Plaintiffs are entitled to recover overcharges on all purchases of Copaxone affected by Teva's unlawful conduct, without regard to the timing of those purchases.

X. CLAIM FOR RELIEF

MONOPOLIZATION (OVERALL SCHEME) (15 U.S.C. § 2)

205. Plaintiffs hereby incorporate by reference the allegations set forth in paragraphs 1 through 204 above.

206. Teva unlawfully monopolized the market for Copaxone and its generic equivalents in the United States.

207. At all relevant times, Teva possessed substantial market power (i.e., monopoly power) with respect to Copaxone and its AP-rated generic equivalents. Teva possessed the power to control prices in the relevant market, to prevent prices from falling in the relevant market, to exclude competitors from the relevant market and to suppress generic competition.

208. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

209. As alleged extensively above, Teva willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than by competing on the merits.

210. Teva's conscious objective was to further its dominance through exclusionary conduct.

211. As explained more fully above, Teva knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by: (a) engaging in serial sham petitioning; (b) entering into exclusionary contracts with PBMs and certain of their associated specialty pharmacies to exclude generic Copaxone from formularies and bar those pharmacies from dispensing generic Copaxone; (c) implementing a coercive product switch to thwart generic competition; (d) engaging in an aggressive DAW campaign that relied in part on misinformation about generic Copaxone, including untrue statements that the FDA-approved generic product was less effective; and (e) paying illegal kickbacks and manipulating commercial copays to suppress generic competition.

212. Teva's anticompetitive conduct was undertaken with the purpose and effect of maintaining Teva's monopoly power in the relevant market, to the detriment of Plaintiffs and other purchasers of the drug.

213. There is no cognizable, non-pretextual, procompetitive justification for Teva's exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Teva were permitted to assert, its conduct is and was broader than necessary to achieve such a purpose.

214. Plaintiffs have been injured and will continue to be injured in their business and property as a result of Teva's unlawful monopolization.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, and for the following relief:

A. A declaration that the conduct alleged above is in violation of section 2 of the Sherman Act;

B. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled as provided by law;

C. Permanent injunctive relief enjoining and restraining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

D. An award of Plaintiffs' costs and reasonable attorneys' fees, as provided by law; and

E. Such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: April 3, 2025

Respectfully submitted,

/s/ *Justin B. Barnard*

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